

**REMARKS/ARGUMENTS**

Claims 1-8, 10-12, and 14-34 are pending in this application. Claims 1-5, 10, 14, 23, 24, 29, 30, 32, and 33 have been amended. Support for the amendments is found on page 3, lines 14-21 of the specification, where the properties of nicotine and oxygen barriers are described. Additional support for the amendments is found within the specification on page 4, line 9, on page 4, line 8, and on page 4, line 13, where the correct spelling of “naphthalate” and “dicarboxylate” may be found. No new matter has been added. Attached hereto is a marked-up version of the changes made to the specification as Appendix A. A marked up version of changes made to the claims by the current amendment is attached as Appendix B. For the convenience of the Examiner, a clean copy of all pending claims is attached as Appendix C.

The issues outstanding in this application are as follows:

- Claims 1, 3-5, 10, 14, 23, 29, 30, 32, and 33 are objected to because of spelling informalities. Examiner states “Dicarboxylate”, “naphthalenate”, and “naphthalenic” are misspelled.
- Claims 32-34 are rejected under 35 U.S.C. § 112 for indefiniteness.
- Claims 1-3, 5-8, 10, 12, and 14-34 are rejected under 35 U.S.C. § 103(a) as being obvious over Cubbage et al. (U.S. Patent No. 5,804,215) in view of Hunter (U.S. Patent No. 6,037,03) and abstract JP 04239607A.
- Claims 1-3, 5-8, 10-12, and 14-34 are rejected under 35 U.S.C. § 103(a) as being obvious over Derr (U.S. Patent No. 6,162,516) in view of Hunter (U.S. Patent No. 6,037,03) and abstract JP 04239607A.

**I. Claims 1, 3-5, 10, 14, 23, 29, 30, 32, and 33 have been amended and no longer contain spelling informalities.**

The Examiner remarks that “dicarboxylate” has been misspelled. Applicants have corrected the misspelling “dicarboxynate” in the claims and have replaced this with “dicarboxylate.” Support for this amendment can be found in the specification on page 4,

line 9. The Examiner remarks that “naphthalenate” has been misspelled. Applicants have corrected the misspelled word “naphtalate.” Applicants suggest that the correct spelling is “naphthalate”, and not “naphthalenate.” The Examiner has pointed out that “naphthalenic” has been misspelled as “naphtalenic”, and Applicants suggest that the correct spelling is “naphthenic”, and this has also been corrected. Support for these amendments can be found on page 4, line 8, and page 4, line 13. In light of these amendments, Applicants believe that in light of the above amendments, the objection based on claim informalities should be withdrawn.

## **II. Claims 32-34 are definite.**

The Examiner has rejected claims 32-34 for indefiniteness under 35 U.S.C. § 112, second paragraph. The Examiner maintains that the phrase “sealing the product with a polymer material” is unclear. Applicants respectfully traverse.

The Examiner herself has ascertained the correct meaning as “the polymer is an adhesive/sealant for the nicotine product.” Support for this meaning can be found on page 7, line 29, and on page 8, line 4. Applicants believe in light of this clarification, the 35 U.S.C. § 112, second paragraph rejection should be withdrawn.

## **III. Claims 1-3, 5-8, 10, 12, and 14-34 are nonobvious over Cubbage.**

The Examiner has rejected claims 1-3, 5-8, 10, 12, and 14-34 under 35 U.S.C. § 103(a) as being obvious over Cubbage et al. (U.S. Patent No. 5,804,215) in view of Hunter (U.S. Patent No. 6,037,03) and abstract JP 04239607A. Applicants respectfully traverse.

Claims 1-5, 10, 14, 23, 24, 29, 30, 32, and 33 have been amended. Support for the amendments is found on page 3, lines 14-21 of the specification, where the properties of nicotine and oxygen barriers are described.

### 1. References Lack Motivation to Combine

The Examiner contends that one skilled in the art would have been motivated to combine all three references. Examiner asserts that all references deal with the production/use of materials having gas barrier properties. However, Applicants respectfully

maintain that there is no motivation to combine the references for the sole purpose that the references reside in analogous art. This is an inappropriate standard. Furthermore, the references lack any hint to combine their teachings to produce Applicant's claimed invention.

Applicants respectfully reiterate that a claim is considered obvious only if the claimed invention as a whole would have been obvious to a skilled artisan. *In re Mayne*, 104 F.3d 1339, 1342 (Fed. Cir. 1997). "It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements." *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997). When relying on a modification of the prior art to reject a claim, it is incumbent upon the Examiner to identify some suggestion in the prior art to make the modification. *In re Mayne*, 104 F.3d at 1342. Although Cubbage teaches products to dispose of nicotine-containing products, there is no suggestion in Cubbage that a gas barrier is required in such a disposal system. Page 4 of the Office Action reads "It is deemed desirable to produce nicotine patch disposal films that are stable so that the nicotine in the patch cannot leach out and become a danger to children or pets that may find it." This statement is the Examiner's opinion, and the opinion of the Examiner that such a modification might be desirable is not a sufficient test for obviousness. The Examiner must point to some suggestion in Cubbage that the modification should be made. However, the Examiner has not found any specific suggestion in Cubbage that such a combination is desirable, and thus has failed to establish a *prima facie* case of obviousness.

Cubbage teaches a method of disposal, aimed at protecting children or pets from nicotine ingestion. Applicants teach a packaging system, aimed at protecting nicotine from environmental exposure. Inherent in the disposal of nicotine, there is no requirement that the nicotine remain biologically active, and thus protected from reaction with oxygen. Thus, there is no suggestion in Cubbage that an oxygen gas barrier is desirable. In fact, such an oxidative reaction could be advantageous in Cubbage's disposal system, whereby reaction with oxygen might assist in the breakdown of nicotine. In contrast, Applicants teach a nicotine and oxygen gas barrier in order to contain nicotine in a biologically active form and keep out environmental gases. Claims 1-5, 10, 14, 23, 24, 29, 30, 32, and 33 have been amended to include such limitations.

Hunter and abstract JP 04239607A teach gas barriers. The disposal system of

Cubbage does not contain any suggestion that nicotine or oxygen barrier properties are desirable. Additionally, there is no teaching of nicotine or oxygen barriers in Hunter and abstract JP 04239607A. Thus, there is no motivation to combine this reference with Hunter and abstract JP 04239607A. Additionally, the combination of Cubbage, Hunter and abstract JP 04239607A does not teach all the limitations of the Applicants' claimed invention. Thus, Applicants' invention is nonobvious over Cubbage.

## 2. References are nonenabling

Applicants assert that the reference does not contain an enabling disclosure because the public did not have complete possession of the claimed invention to combine knowledge in the art with the Cubbage, Hunter, and JP 04239607A disclosures to produce the claimed invention until Applicants' disclosure. *In re Donohue*, 766 F.2d 531, 266 USPQ 6191 (Fed. Cir. 1985).

*Latent.* Applicants' invention deals with a barrier against nicotine gas, which is nonobvious from references dealing with barriers against generic gases. Hunter does not teach use of LCPs as a nicotine barrier, but rather as a generic gas barrier. Materials which act as a barrier to one type of gas do not necessarily act as a barrier to all gases. For example, a rubber balloon has different gas barrier properties for helium and oxygen, and will contain oxygen for a much longer period than it is able to contain helium. It is necessary to test the effectiveness of gas barriers against individual gases. Applicants describe such tests for the effectiveness of LCPs, as well as PEN, as a nicotine barrier in the specification on Table 1, page 6. Similarly, abstract JP 04239607A teaches PEN and generic gas barrier activity, but is nonenabling for a nicotine barrier. Claims 1-5, 10, 14, 23, 24, 29, 30, 32, and 33 have been amended to include limitations for nicotine and oxygen barrier properties. Cubbage teaches a nicotine disposal system, which also is nonenabling for nicotine or oxygen barrier properties. Thus, the combination of Hunter, Cubbage, and abstract JP 04239607A is nonenabling for the Applicants' invention, namely a nicotine packaging system comprising nicotine and oxygen barriers.

In light of the above arguments, Applicants respectfully request withdrawal of the 35 U.S.C § 103(a) rejection.

**IV. Claims 1-3, 5-8, 10-12, and 14-34 are nonobvious over Derr.**

The Examiner has rejected claims 1-3, 5-8, 10-12, and 14-34 under 35 U.S.C § 103(a) as being obvious over Derr et al. (U.S. Patent No. 6,162,516) in view of Hunter (U.S. Patent No. 6,037,03) and abstract JP 04239607A. Applicants respectfully traverse.

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

Derr teaches a holding pouch for smokeless tobacco. Applicants teach a material and a method for packaging tobacco products. Inherent in Derr's invention is that it allows the "normal use of smokeless tobacco" (Abstract, line 10). Normal use of smokeless tobacco includes the ability of the tobacco to come into contact with saliva and to be absorbed into the bloodstream. Applicants teach a packaging method which completely encloses a nicotine-containing product, leaving it invulnerable to saliva access. Applicants specifically teach that the method uses a packaging material that includes a water barrier (page 3, lines 24-28 and page 5, line 12). Additionally, Applicants teach a material with a gas barrier to nicotine (page 3, lines 15-17 and page 5, line 13). Thus, to modify Derr as Applicant teaches would result in a smokeless tobacco product completely enclosed in a water, oxygen, and nicotine impermeable casing. Claims 1-5, 10, 14, 23, 24, 29, 30, 32, and 33 have been amended to include limitations for nicotine and oxygen barrier properties. Such a casing would not allow the normal use of smokeless tobacco, as no nicotine would be able to be absorbed into the bloodstream. Thus, neither the material nor the packaging method would be suitable for Derr. Such a modification would thus render Derr unsuitable for its intended purpose of the normal use of smokeless tobacco. Thus, Applicants' invention must be nonobvious over Derr.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 It is inappropriate to combine Derr with Hunter and JP 04239607A, as Derr teaches away from Applicants. Combining Derr, Hunter and JP 04239607A cannot be desirable if the modification of Derr in view of Hunter and JP 04239607A renders Derr unsuitable for its intended use.

In light of the above arguments, Applicants respectfully request withdrawal of the 35 U.S.C § 103(a) rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. 10105701 from which the undersigned is authorized to draw.

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Respectfully submitted,

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## Appendix A

### Changes made in the Abstract:

A material for packaging a nicotine-containing product comprising a polymer based on dimethyl-2,6-naphthalene [dicarboynate] dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, such as polyethylene [naphthalate] naphthalate (PEN) or polytrimethylene [naphthalate] naphthalate (PTN), or a liquid crystal polymer (LCP). The material may be laminated to another polymer or to metal foil.

### Changes made in the paragraph on starting on page 2, line 14, and ending on page 2, line 20:

The material of the invention comprises polyethylene [naphthalate] naphthalate, polytrimethylene [naphthalate] naphthalate and/or a liquid crystal polymer, LCP, and has excellent characteristics of oxygen, water, and nicotine impermeability. Due to the temperature ranges the polymers of the invention are favorable to process and will have an acceptable price. The material of the invention is known per se, but its excellent nicotine barrier properties have not been known. Neither has its use for making packages for nicotine-containing products been contemplated.

### Changes made in the paragraph starting on page 4, line 4, and ending on page 4, line 4:

The first of these materials is PEN, polyethylene [naphthalate] naphthalate.

### Changes made in the paragraphs on starting on page 4, line 8, and ending on page 4, line 17:

PEN is a polyester based on dimethyl-2,6-naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers. Dimethyl-2,6-naphthalene [dicarboxynate] dicarboxylate and -2,6-naphthalene dicarboxylic acid monomers are e.g. sold by Amoco under the trade name NDC and NDA-monomer respectively. PEN is semicrystalline and is a glass polymer at room temperature.

There are other polymers such as PTN (polytrimethylene naphthalate) which are based on the same monomers. PTN differs from PEN only in that the ethylene chain has been exchanged to a propylene chain. It is envisageable to use polymers comprising both

dimethyl-2,6-naphthalene [dicarboxynate] dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers.

**Appendix B**

1. (Amended twice) A material for packaging a nicotine-containing product comprising a polymer based on dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] or 2,6-naphthalene dicarboxylic acid monomers, wherein said polymer comprises a nicotine and oxygen barrier.
2. (Amended twice) A material for packaging a nicotine-containing product comprising a liquid crystal polymer (LCP), wherein said polymer comprises a nicotine and oxygen barrier.
3. (Amended twice) The material according to claim 1, wherein the polymer is polyethylene naphthalate [naphtalate] (PEN).
4. (Amended twice) The material according to claim 1, wherein the polymer is polytrimethylene naphthalate [naphtalate] (PTN).
5. (Amended twice) The material according to claim 2, wherein the LCP comprises hydroxy benzoic acid and hydroxy naphthalenic [naphtalenic] acid.
10. (Amended twice) A method of packaging a nicotine containing product comprising the step of providing a polymer material for a mould or an equivalent to cast the nicotine containing product into its final shape upon solidification in the package, wherein the polymer material is based upon dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] or 2,6-naphthalene dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.
14. (Amended) A material for packaging a nicotine-containing product, comprising a polymer based on a combination of dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] and 2,6-naphthalene dicarboxylic acid monomers, wherein said polymer comprises a nicotine and oxygen barrier.
23. (Amended) A method of packaging a nicotine containing product comprising the step of enclosing totally the product with a polymer material, wherein the polymer material is a

material based on dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] or 2,6-naphthalene [naphthalene] dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.

24. (Amended) The method according to claim 23, wherein the polymer is polyethylene naphthalate [naphthalate] (PEN), polytrimethylene naphthalate [naphthalate] (PTN) or a liquid crystal polymer (LCP).

29. (Amended) A method of packaging a nicotine containing product comprising the step of enclosing partially the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] or 2,6-naphthalene [naphthalene] dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.

30. (Amended) The method according to claim 29, wherein the polymer is polyethylene naphthalate [naphthalate] (PEN), polytrimethylene naphthalate [naphthalate] (PTN) or a liquid crystal polymer (LCP).

32. (Amended) A method of packaging a nicotine containing product comprising the step of sealing the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxylate [dicarboxynate] or 2,6-naphthalene [naphthalene] dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.

33. (Amended) The method according to claim 32, wherein the polymer is polyethylene naphthalate [naphthalate] (PEN), polytrimethylene naphthalate [naphthalate] (PTN) or a liquid crystal polymer (LCP).

**Appendix C**

1. A material for packaging a nicotine-containing product comprising a polymer based on dimethyl-2,6 naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, wherein said polymer comprises a nicotine and oxygen barrier.
2. A material for packaging a nicotine-containing product comprising a liquid crystal polymer (LCP), wherein said polymer comprises a nicotine and oxygen barrier.
3. The material according to claim 1, wherein the polymer is polyethylene naphthalate (PEN).
4. The material according to claim 1, wherein the polymer is polytrimethylene naphthalate (PTN).
5. The material according to claim 2, wherein the LCP comprises hydroxy benzoic acid and hydroxy naphthalenic acid.
6. The material according to claim 1, further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
7. The material according to claim 1, wherein the material is laminated with one or more metals or polymer foils.
8. The material according to claim 7, wherein the metal is aluminum foil.
10. A method of packaging a nicotine containing product comprising the step of providing a polymer material for a mould or an equivalent to cast the nicotine containing product into its final shape upon solidification in the package, wherein the polymer material

is based upon dimethyl-2,6 naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.

11. The method according to claim 10, wherein the final form of the nicotine containing product is a tablet or a lozenge.

12. The material according to claim 1, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.

14. A material for packaging a nicotine-containing product, comprising a polymer based on a combination of dimethyl-2,6 naphthalene dicarboxylate and 2,6-naphthalene dicarboxylic acid monomers, wherein said polymer comprises a nicotine and oxygen barrier.

15. The material according to claim 2 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).

16. The material according to claim 14 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).

17. The material according to claim 14, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.

18. The material according to claim 14, wherein the material is laminated with one or more metals or polymers.

19. The material according to claim 18, wherein the metal is aluminum foil.

20. The material according to claim 2, wherein the material is laminated with one or more metals or polymers.

21. The material according to claim 20, wherein the metal is aluminum foil.
22. The material according to claim 2, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.
23. A method of packaging a nicotine containing product comprising the step of enclosing totally the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.
24. The method according to claim 23, wherein the polymer is polyethylene naphthalate (PEN), polytrimethylene naphthalate (PTN) or a liquid crystal polymer (LCP).
25. The method according to claim 23 further comprising other polymer(s), selected from the group consisting of polyacrylonitrile (PAN), polyamide (PA), polyvinylidene chloride (PVDC), fluoropolymers, ethylene vinyl alcohol copolymer (EVOH), polyvinyl alcohol (PVA), ionomers, polyethylene (PE), and polypropylene (PP) and polyethylene terephthalate (PET).
26. The method according to claim 23, wherein the material is laminated with one or more metals or polymers.
27. The method according to claim 23, wherein the metal is aluminum foil.
28. The method according to claim 23, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.
29. A method of packaging a nicotine containing product comprising the step of enclosing partially the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.
30. The method according to claim 29, wherein the polymer is polyethylene naphthalate (PEN), polytrimethylene naphthalate (PTN) or a liquid crystal polymer (LCP).
31. The method according to claim 29, wherein the nicotine containing product is a patch,

a chewing gum, a tablet, a spray, or an inhaler.

32. A method of packaging a nicotine containing product comprising the step of sealing the product with a polymer material, wherein the polymer material is a material based on dimethyl-2,6 naphthalene dicarboxylate or 2,6-naphthalene dicarboxylic acid monomers, and wherein said polymer comprises a nicotine and oxygen barrier.

33. The method according to claim 32, wherein the polymer is polyethylene naphthalate (PEN), polytrimethylene naphthalate (PTN) or a liquid crystal polymer (LCP).

34. The method according to claim 32, wherein the nicotine containing product is a patch, a chewing gum, a tablet, a spray, or an inhaler.